



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-23-1309; Docket No. CDC-2023-0047]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of Government information, invites the general public and other Federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Enterprise Laboratory Information Management System (ELIMS). This data collection is used by CDC to record specimen metadata and patient data related to test order requests submitted by external partners (SPHLs, International organizations, Federal institutions, hospitals, doctor's offices, etc.) to the CDC Infectious Diseases testing laboratories.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2023-0047 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number.

CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal

(www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Enterprise Laboratory Information Management System (ELIMS) (OMB Control No. 0920-1309, Exp. 11/30/2023) – Revision - National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The collection of specimen information designated for testing by the CDC occurs on a regular and recurring basis (multiple times per day) using an electronic PDF file called the CDC Specimen Submission 50.34 Form or an electronic XSLX file called the Global File Accessioning Template. Hospitals, doctor's offices, medical clinics, commercial testing labs, universities, State public health laboratories, U.S. Federal institutions, and foreign institutions use the CDC Specimen Submission Form 50.34 when submitting a single specimen to CDC Infectious Diseases laboratories for testing. The CDC Specimen Submission 50.34 Form consists of over 200 data entry fields (of which five are mandatory fields that must be completed by the submitter) that captures information about the specimen being sent to the CDC for testing. The type of data captured on the 50.34 Form identifies the origin of the specimen (human, animal, food, environmental, medical device or biologic), CDC test order name/code, specimen information, patient information (as applicable), animal information (as applicable) information about the submitting organization requesting the testing, patient history (as applicable), owner information and animal history (as applicable), and epidemiological information. The collection of this type of data is pertinent to ensuring a specimen's testing results are linked to the correct patient and the final test reports are delivered to the appropriate submitting organization to aid in

making proper health-related decisions related to the patient. Furthermore, the data provided on this form may be used by the CDC to identify sources of potential outbreaks and other public-health related events. When the form is filled out, a user in the submitting organization prints a hard copy of it that will be included in the specimen's shipping package sent to the CDC. The printed form has barcodes on it that allow the CDC testing laboratory to scan its data directly into ELIMS where the specimen's testing lifecycle is tracked and managed.

Likewise, the Global File Accessioning Template records the same data as the 50.34 Form but provides the capability to submit information for a batch of specimens (typically 50-1,000 specimens per batch) to a specific CDC laboratory for testing. The CDC testing laboratory electronically uploads the Global File Accessioning Template into ELIMS where the batch of specimens are then logged and are ready to be tracked through their respective testing and reporting workflow.

CDC requests OMB approval for an estimated 2,153 annual burden hours. There is no cost to respondents other than their time for participation.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Medical Scientists, Except Epidemiologists, State Public Health Lab, Medical Assistant, Doctor's Office/Hospital	CDC Specimen Submission 50.34 Form	2,098	12	5/60	2,098
Medical Assistant, Doctor's Office/Hospital	Global File Accessioning Template	15	11	20/60	55
Total					2,153

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Public Health Ethics and Regulations,
Office of Science,
Centers for Disease Control and Prevention.

[FR Doc. 2023-12360 Filed: 6/8/2023 8:45 am; Publication Date: 6/9/2023]